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|---|-------------|----------------------|---------------------|------------------|
| 10/071,411  | 02/07/2002  | Glenn Barnes         | MRI-021             | 1738             |
| 959   | 7590        | 12/09/2003           | EXAMINER            |                  |
| LAHIVE & COCKFIELD, LLP.<br>28 STATE STREET<br>BOSTON, MA 02109 |             |                      | WILDER, CYNTHIA B   |                  |
|   |             |                      | ART UNIT            | PAPER NUMBER     |
|   |             |                      | 1637                |                  |

DATE MAILED: 12/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

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## Office Action Summary

Application No.

10/071,411

Applicant(s)

BARNES ET AL.

Examiner

Cynthia B. Wilder, Ph.D.

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 02 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 27-36 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 27-36 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election without traverse of Group III, claims 27-36 and cancellation of claims 1-26 submitted on September 2, 2003 is acknowledged. Applicant's election with traverse of SEQ ID NO: 5 submitted on September 2, 2003 is acknowledged. However upon further consideration, the restriction requirement for SEQ ID NOS: 4-6 have been withdrawn. Accordingly, claims 27-36 and SEQ ID NOS: 4-6 are pending in the instant invention.

### ***Specification***

2. The use of the trademarks "Genbank" at page 12, line 28 and "SYBR Green II", "Molecular Probes", "Fluoroimager" and "Molecular Dynamics" at page 66, line 20 have been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

### ***Information Disclosure Statement***

3. The information disclosure statement filed October 15, 2002 is acknowledged. However, copies of the non-patent literatures cited therein are not found in the instant application. The examiner is making efforts to locate these references; however, resubmission of these documents, if possible, by applicant would facilitate their consideration and would greatly be appreciated by the examiner. Applicant has considered all patented documents. A signed copy

Art Unit: 1637

of the PTO-1449 will be mailed as soon as the examiner obtains copies of the references. The examiner regrets any inadvertent inconveniences.

***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 27-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(a) Claims 27-36 are indefinite at "5-LO" in claims 27 because abbreviations often have more than one meaning in the art. It is suggested reciting the full name of the abbreviation in the claim as supported by the specification.

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 27-31, 35 and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by Drazen et al. (W0 97/42347, 13 November 1997). The claims are drawn to a method for determining the identity of an allelic variant of 5-LO gene sequence in a nucleic acid obtained from a patient, wherein the sample comprises a 5-LO gene sequence, comprising contacting a

Art Unit: 1637

sample nucleic acid from the patient with a probe or primer having a sequence which is complementary to a 5-LO gene sequence, wherein the allelic variant comprises one or more nucleotide sequence selected from the group consisting of those set forth in SEQ ID NO: 4, SEQ ID NO: 5 or SEQ ID NO: 6, or the complements thereof, thereby determining the identity of the allelic variant.

Drazen et al teach a method for determining the identity of an allelic variant of 5-lipoxygenase gene (5-LO gene) in a nucleic acid obtained from a patient, wherein the sample comprises a 5-LO gene sequence, comprising contacting the sample nucleic acid from the patient with a probe or primer having a sequence which is complementary to a 5-LO gene sequence, wherein the allelic variant comprises one or more nucleotide sequence selected from the group consisting of SEQ ID NO: 4 (see sequence alignment attached to reference and table 1) and SEQ ID NO: 6 (see sequence alignment attached to reference and table 1) or complement thereof, thereby determining the identity of the allelic variant (see pages 8-13 beginning at line 14 and Example 1 beginning at page 17).

Regarding claim 28, Drazen et al teach the method of claim 27, wherein determining the identity of the allelic variant comprises determining the identity of at least one nucleotide at any of the nucleotide residues comprising residues 292 to 727 of the 5-LO gene sequence (SEQ ID NO: 1 (see page 18 and SEQ ID NO: 1 -page 40). The polymorphic region comprising residues 292-727 encompasses the residues at 472-477 and 559.

Regarding claim 29, Drazen et al teach the method of claim 27, wherein determining the nucleotide content comprises sequencing the nucleotide sequence (page 9, lines 15-18).

Art Unit: 1637

Regarding claim 30, Drazen et al teach the method of claim 27, wherein determining the identity of the allelic variant comprises performing a restriction enzyme site analysis (page 10, lines 7-9 and 21).

Regarding claim 31, Drazen et al teach the method of claim 27, wherein determining the identity of the allelic variant is carried out by single-stranded conformation polymorphism (page 9, lines 15-17).

Regarding claim 35, Drazen et al teach the method of claim 27, wherein the probe or primers comprises a nucleotide sequence from about 15 to about 30 nucleotides long (see Example 1, pages 18-19, Table 1).

Regarding claim 36, Drazen et al teach the method of claim 27, wherein the probe or primer is labeled (page 18, line 13-15; page 19, lines 22-23).

In view of the foregoing, Drazen et al. meets the limitations of claims 27-31, 35, and 36 of the instant invention.

***Claim Rejections - 35 USC § 102/103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 32-34 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Drazen et al. as previously applied above. Claims 32-34 are drawn to an embodiment of claim 27, wherein determining the identity of the allelic variant is carried out by allele specific hybridization (clm 32) or by primer specific extension (clm 33),

Art Unit: 1637

or by oligonucleotide ligation assay (clm 34). Drazen et al teach a method for determining the identity of an allelic variant of 5-lipoxygenase gene (5-LO gene) in a nucleic acid obtained from a patient, wherein the sample comprises a 5-LO gene sequence, comprising contacting the sample nucleic acid from the patient with a probe or primer having a sequence which is complementary to a 5-LO gene sequence, wherein the allelic variant comprises one or more nucleotide sequence selected from the group consisting of SEQ ID NO: 4 and SEQ ID NO: 6 or complement thereof, thereby determining the identity of the allelic variant (see pages 8-13 beginning at line 14 and Example 1 beginning at page 17). Drazen et al further teach wherein the identity of the allelic variant is performed by single-stranded conformational polymorphism, single sequence length polymorphism and DNA sequencing techniques (page 9, lines 15-18 and Example 1). Drazen et al additionally state that those of ordinary skill in the art will recognize that the particular methods of polymorphism identification described in Example 1 are not intended to be limiting to the present invention. Drazen et al teach that any of a variety of other techniques could alternatively be used (page 10, lines 4-11). The preceding rejection is based on the judicial precedent following *In re Fitzgerald*, 205 USPQ 594 because the reference is silent with regards to the "allelic variants being identified by allele specific hybridization or by primer specific extension, or by oligonucleotide ligation assay". However, these techniques are deemed inherent by the reference of Drazen et al. in the teaching that "any of a variety of other techniques could alternatively be used" to determine the polymorphic sequences of the gene interest. Likewise the recited techniques of claims 32-34 are well known and commonly performed in the prior art for identifying polymorphic/allelic variants. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the claimed invention that any of the

Art Unit: 1637

claimed techniques, which are well known in the art for identifying polymorphic variants, could have been performed to obtain the allelic variants of the instant invention.

***Conclusion***

10. No claims are allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia B. Wilder, Ph.D. whose telephone number is (703) 305-1680. After January 14, 2004, the examiner may be reached at (571) 272-0791. The examiner works a flexible schedule and can be reached by phone and voice mail. Alternatively, a request for a return telephone call may be emailed to [cynthia.wilder@uspto.gov](mailto:cynthia.wilder@uspto.gov). Since email communications may not be secure, it is suggested that information in such requests be limited to name, phone number, and the best time to return the call.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (703) 308-1119. The official fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308 0196.

  
**CYNTHIA WILDER**  
**PATENT EXAMINER**

Cynthia B. Wilder, Ph.D.  
Art Unit 1637